

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE**

**IN RE: VALSARTAN, LOSARTAN,
AND IRBESARTAN PRODUCTS
LIABILITY LITIGATION**

This Document Relates to All Actions

MDL No. 2875

Honorable Robert B. Kugler,
District Court Judge

Honorable Karen Williams
Magistrate Judge

**WHOLESALE DEFENDANTS' OPPOSITION TO PLAINTIFFS'
MOTION FOR LEAVE TO AMEND MASTER COMPLAINTS**

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INTRODUCTION

Beginning on December 18, 2020, this Court entered six Orders and corresponding Opinions ruling on Wholesalers' Motions to Dismiss Plaintiffs' Personal Injury Master Complaint ("PIMC"), Second Amended Economic Loss Master Complaint ("ELMC"), and Medical Monitoring Master Complaint ("MMMC"). *See* MTD Ords. and Ops. 1-6. In these rulings, the Court dismissed without prejudice multiple claims against Wholesalers¹ due to Plaintiffs' failure to properly plead these claims. The Court provided thorough and detailed Opinions outlining its reasoning for dismissing the claims and offering Plaintiffs guidance on how to amend and cure certain deficiencies. Plaintiffs do not follow the Court's instructions; they do not because they cannot make these allegations in good faith.

On April 12, 2021, Plaintiffs filed a Motion for Leave to Amend Master Complaints, attaching as exhibits three proposed amended master complaints.² Despite being given four months' time and a clear "roadmap" from the Court as to how to correct the pleadings, Plaintiffs do not heed the Court's advice and instead "double down" on several of the same pleading deficiencies that got many of their

¹ The named Wholesalers are AmerisourceBergen Corporation, Cardinal Health, Inc., and McKesson Corporation.

² This Opposition refers to the Proposed Economic Loss Master Class Complaint, Dkt. 1148-3, as the PELMC; the Proposed Medical Monitoring Master Class Complaint, Dkt. 1148-5, as the PMMMC; and the Proposed Personal Injury Master Complaint, Dkt. 1148-1, as the PPIMC.

claims dismissed in the first place. Plaintiffs’ few attempts to substantively amend their claims boil down to the insertion of conclusory statements, shotgun allegations, and far-fetched “warranties” crafted out of website statements or package labeling materials Wholesalers are legally-precluded from altering. Plaintiffs still lack Article III standing. Their unjust enrichment and warranty claims are flatly insufficient. Plaintiffs do not appropriately or specifically plead their fraud claims and do not include facts sufficient to support their negligent misrepresentation claims. Plaintiff still cannot articulate a duty owed to them by Wholesalers–pass-through entities in the supply chain–in order to support their negligence claims. And Plaintiffs’ “amended” failure to warn and strict liability claims do not comply with the Court’s very clear Orders. As a result, none of Plaintiffs’ derivative claims should survive.

Plaintiffs cannot correct their pleadings. As such, allowing Plaintiffs to file their proposed amended complaints would be futile. For these reasons, and as further set forth below, Plaintiffs’ Motion for Leave to Amend should be denied and the previously-dismissed claims against Wholesalers should be dismissed with prejudice.

LEGAL STANDARD

A court may deny leave to amend when the proposed amendment would be futile – *i.e.*, when the amended complaint would not survive a motion to dismiss for failure to state a claim. *Budhun v. Reading Hosp. & Med. Ctr.*, 765 F.3d 245, 259

(3d Cir. 2014). Indeed, to determine if an amendment is futile, a court must apply the same standard set out in Federal Rule of Civil Procedure 12(b)(6). *Travelers Indem. Co. v. Dammann & Co.*, 594 F.3d 238, 243 (3d Cir. 2010). As such, an amended complaint fails to state a claim if the plaintiff “is unable to plead enough facts to state a claim to relief that is plausible on its face.” *Budhun*, 765 F.3d at 259 (internal citations and quotation omitted).

ARGUMENT

I. PLAINTIFFS’ PROPOSED AMENDMENTS DO NOT MEET THEIR OBLIGATION TO PLEAD STANDING AGAINST WHOLESALERS (PELMC Counts 1-16 and PMMMC Counts 1-8)

In MTD Opinion and Order 2, this Court recognized the several ways in which Plaintiffs failed to establish the bedrock constitutional requirement of standing. As a result, the Court dismissed without prejudice all claims against Wholesalers in the ELMC and MMHC for lack of Article III standing, as the individual named proposed class representative plaintiffs “failed to trace their injuries to many of the Defendants in this case beyond conclusory allegations.” MTD Op. 2 at 17. The Court also dismissed without prejudice all claims in the ELMC and MMHC arising under the laws of states for which there was no named class representative, as Plaintiffs do not “have standing to assert claims under the laws of states where they do not reside and were not injured.” *Id.* at 19. Despite the significant length of time Plaintiffs have had to recruit class representatives and address these pleading deficiencies, the

PELMC and PMMMC fail to correct them; Plaintiffs *still* lack any class representative for most states *and* lack a single class representative who can demonstrate traceability and standing to bring specific state-law-based claims against individual Wholesalers in that state. For the reasons stated in Mfrs.’ Mem. Section III.B.1-4 and Pharmacy Defs.’ Mem. Section II, which Wholesalers incorporate by reference as if set forth fully herein, as well as additional arguments below, Plaintiffs fail to establish standing and Plaintiffs’ Motion for Leave to Amend should be denied and claims against Wholesalers should be dismissed with prejudice.

A. In Disregard of this Court’s Rulings, Plaintiffs Still Assert State-Specific Claims Under the Laws of Unrepresented States

Plaintiffs’ amended complaints still purport to bring claims under the laws of all 50 states, the District of Columbia, and Puerto Rico, but—in direct contravention of this Court’s prior rulings—still do not name a class representative who could represent each of those jurisdictions. Plaintiffs have had sufficient time and opportunity to locate and name Plaintiffs sufficient to establish standing in all states and territories under the laws of which Plaintiffs purport to bring claims. Plaintiffs’ repeated failures to do so demonstrate that they cannot establish standing in those remaining states and territories and amendment is futile. For these reasons, along with the reasons set forth in the Mfrs.’ Mem. Section III.B.1-4 and Pharmacy Defs.’ Mem. Section II, which Wholesalers incorporate by reference:

- *All of the PELMC's claims arising out of the laws of the following states fail for want of standing, which cannot be cured by amendment, and should be dismissed with prejudice as to Wholesaler Defendants AmerisourceBergen, Cardinal Health, and McKesson:* Alaska, Arizona, Arkansas, Colorado, Delaware, District of Columbia, Hawaii, Idaho, Iowa, Maryland, Michigan, Missouri, Montana, Nebraska, Nevada, New Hampshire, North Dakota, Oklahoma, Oregon, Puerto Rico, Rhode Island, South Carolina, South Dakota, Tennessee, Utah, Vermont, Washington, West Virginia, Wisconsin, Wyoming.
- *All of the PMMMC's claims arising out of the laws of the following states fail for want of standing, which cannot be cured by amendment, and should be dismissed with prejudice as to Wholesalers AmerisourceBergen, Cardinal Health, and McKesson:* Alabama, Alaska, Arizona, Arkansas, Connecticut, Delaware, District of Columbia, Georgia, Hawaii, Idaho, Indiana, Iowa, Kentucky, Louisiana, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Puerto Rico, Rhode Island, South Carolina, South Dakota, Tennessee, Utah, Vermont, Virginia, Washington, Wisconsin, Wyoming.

B. The Majority of Named Class Representatives Still Fail to Allege Any Traceability or Facts Supporting Standing as to the Named Wholesalers.

Plaintiffs' continued failure to meet their standing burdens and the futility of the proposed amendments are particularly clear when broken down by the numbers.

In the PELMC, of the 42 proposed consumer class representatives:

- 14.28% (6/42) fail to allege traceability to or involvement by any Wholesaler whatsoever
- 54.76% (23/42) fail to allege traceability to or involvement by any named Wholesaler, alleging only the involvement of "John Doe Wholesaler"
- 38.09% (16/42) make only high-level, non-NDC-specific allegations of traceability to or involvement by one or more of the named Wholesalers

In the PMMMC, of the 16 proposed class representatives:

- 18.75% (3/16) fail to allege traceability to or involvement by any Wholesaler whatsoever
- 31.25% (5/16) fail to allege traceability to or involvement by any named Wholesaler, alleging only the involvement of “John Doe Wholesaler”
- 50% (8/16) make only high-level, non-NDC-specific allegations of traceability to or involvement by one or more of the named Wholesalers

Thus, 69.04% (29/42) of the PELMC’s named consumer class representatives and 50% (8/16) of the PMMMC’s named class representatives do not even attempt to fulfill Plaintiffs’ standing and traceability burdens.³ These numbers demonstrate the futility of Plaintiffs’ proposed amendments.

1. For Class Representatives Who Fail to Mention or Allege Involvement by Any Wholesaler, Plaintiffs Concede Those Plaintiffs Lack Standing as to Wholesalers

As detailed above, many class representatives in the PELMC and PMMMC do not even mention Wholesalers, let alone allege traceability or standing as to Wholesalers. For example, PELMC putative class representative Ron Molinaro alleges that he purchased VCDs “sold, manufactured, or distributed into the United

³ Notably, Plaintiffs themselves admit that each Wholesaler is only even allegedly connected to a fraction of putative class representatives. *See* redlined PELMC ¶ 152 (“The VCDs distributed by Defendant Cardinal Health, Inc. included VCDs . . . ultimately sold to Plaintiff Gilder, Nelson, and other similarly situated customers”), ¶ 155 (“The VCDs distributed by Defendant McKesson Corporation included VCDs . . . which were ultimately sold to Plaintiffs Borkowski, Cacaccio, Semmel, Kaplan, Lee, Longwell, Neal, Nelson, Wineinger, and other similarly situated consumers.”), ¶ 158 (“The VCDs distributed by Defendant AmerisourceBergen Corporation included VCDs . . . which were ultimately sold to Plaintiffs Bruner, Duffy, Erwin, Powell, Roberts and other similarly situated consumers.”); PMMMC ¶¶ 500, 502, 504 (pp. 61-62).

States drug supply chain by the ZHP Defendants”; that were “manufactured by Defendant ZHP, and sold in the United States by Defendant Solco, with assistance from Defendant Huahai US and Defendant Princeton”; and that “[a]t least some of this ZHP Product ultimately purchased by Plaintiff Molinaro was purchased from Defendant ZHP by Retail Pharmacy Defendant CVS (among other Retail Pharmacy Defendants).” Redlined PELMC ¶ 28. Critically, Plaintiff Molinaro nowhere alleges any Wholesaler—known or unknown, named Defendant or non-party—was involved, let alone that his alleged injuries are traceable to any Wholesaler. And Plaintiff Molinaro is just one of many class representatives whose claims are similarly deficient. By failing to make any such allegations in the PELMC and PMMMC for those class representatives—despite the Court’s clear guidance in MTD Order 2—Plaintiffs concede that those Plaintiffs lack standing as to Wholesalers. As a result, the Court should dismiss with prejudice the claims of the 6 PELMC⁴ and 3 PMMMC⁵ putative class representatives who admittedly lack standing as to Wholesalers, as shown in Mfrs.’ Charts and Wholesalers’ Charts, attached as exhibits to the respective Briefs.

⁴ The 6 PELMC putative class representatives who admittedly lack standing as to Wholesalers are: Ron Molinaro, Joseph Kessinger, Sandy Bell, Flora McGilvery, Gary Burnett, and Miranda Dudley.

⁵ The 3 PMMMC putative class representatives who admittedly lack standing as to Wholesalers are: Anthony Martinez, Michael Rives, and Robert Fields.

2. By Failing to Allege the Particular Product(s) or Named Wholesaler(s) Involved, Plaintiffs Fail to Establish Traceability and Standing

For other proposed class representatives in the PELMC and the PMMMC, Plaintiffs make a feeble attempt to establish traceability and standing as to Wholesalers by alleging—without an iota of factual support—that “John Doe Wholesaler(s)” may have sold “at least some” unidentified product(s). Factually unsupported allegations that an unknown number of unnamed John Doe Wholesalers may have sold some unidentified product(s) is insufficient to establish traceability or Article III standing as to Wholesalers, so leave to amend should be denied.

a. Plaintiffs do not sufficiently identify the product(s) they allege caused them harm

All 42 PELMC and all 16 PMMMC class representatives fail to identify with particularity the product(s) they allege caused them harm. As a result, the PELMC and PMMMC continue to run afoul of this Court’s rulings in MTD Opinion 2 and the particularity requirement of traceability. In *In re Franklin Mut. Funds Fee Litig.*, the plaintiffs’ alleged injuries stemmed from their ownership of over 100 different mutual funds. 388 F.Supp.2d 451, 456 (D.N.J. 2005). The court dismissed Plaintiffs’ claims for lack of traceability stating that Article III standing was not met because it was “unclear from the Complaint . . . *which* directors, investment advisers, and principal underwriters and distributors are associated with *which* mutual funds,” or stated another way, “Plaintiffs did not link an investment adviser defendant,

distributor defendant, or director defendant to a *particular fund*.” *Id.* at 456, 462 (emphasis added).

Concluding its analysis of *In re Franklin* in MTD Opinion 2, this Court remarked: “The same rationale applies here. Plaintiffs have failed to trace their injuries to many of the Defendants in this case beyond conclusory allegations that lump Defendants together.” Plaintiffs’ amendments do not resolve this issue, as the PELMC and PMMMC provide nothing more than factually unsupported conclusory allegations that lump together different unknown NDCs and Defendants, which do not and cannot trace particular NDCs to particular Defendants.

For example, PELMC class representative Sandra Kelly alleges that, “[d]uring the class period, [she] paid money for one or more of Defendants’ VCDs, including purchases of VCDs manufactured, distributed, or sold by ZHP Defendants” and that “the product sold by the ZHP Defendants (“ZHP Product”) *bore a unique NDC* which denoted that it was indeed sold, manufactured, or distributed into the United States drug supply chain by the ZHP Defendants.” Redlined PELMC ¶ 48 (emphasis added). Although Plaintiffs affirmatively admit that the product has a unique NDC, Plaintiffs make no attempt to provide that NDC, instead vaguely labeling the unknown product(s) the “ZHP Product,” and acknowledging that the “ZHP Product” may in fact include multiple ZHP NDCs. *See id.* The ambiguous “ZHP Product” thus impermissibly encompasses and lumps together several (if not hundreds) of different

individual NDCs, which ostensibly were not distributed and sold by the exact same Wholesalers and/or Pharmacy Defendants. Like the product at issue in *In re Franklin*, the VCDs are not traceable to Defendants' alleged misconduct in the aggregate. And as the Court in *In re Franklin* required the plaintiffs to link each defendant to a particular product in order to satisfy traceability, so too should this Court require Plaintiffs here to link particular Defendants to each particular NDC that allegedly caused that Plaintiff's injuries.

Two additional insufficiencies compound the lack of particularity and traceability: First, Plaintiffs concede that the unknown "ZHP Product(s)" may not be the only Manufacturer's VCD product purchased. Redlined PELMC ¶ 48 (Plaintiff Kelly "paid money for one or more of Defendants' VCDs, including purchases of VCDs manufactured, distributed, or sold by ZHP Defendants."). Second, with respect to Wholesalers, Plaintiffs allege only that "[a]t least some" of this amorphous "ZHP Product" "was purchased from Defendant ZHP by John Doe Wholesalers." *Id.* (emphasis added). Thus, not only does the term "ZHP Product" impermissibly lump together an unknown number of ZHP's NDCs, but Plaintiffs also admit that the supply chain may indeed be different for each of these unknown NDCs and, thus, that John Doe Wholesalers may not be associated with each NDC encompassed by the term "ZHP Product." Had the plaintiffs in *In re Franklin* simply alleged that "at least some" of the lumped-together mutual funds were linked to John

Doe defendants, the court would have dismissed the claims as not being traceable to each particular mutual fund. Likewise, this Court should deny leave to amend and dismiss the claims with prejudice because the PELMC and PMMMC fail—on multiple fronts—to allege the product(s) at issue with particularity or the Wholesaler(s) allegedly associated with them.

b. Unsupported Allegations that an Unknown Number of Named or Unnamed John Doe Wholesalers May Have Sold Unidentified Product(s) Are Insufficient to Establish Traceability or Article III Standing

All of the putative class representatives in the PELMC and PMMMC suffer from the same particularity and traceability insufficiencies outlined above, but, additionally, 23 of the class representatives in the PELMC (54.76%) and 5 in the PMMMC (31.25%) do not name any Wholesaler with particularity. Returning to Plaintiff Kelly discussed above, she alleges—with zero factual support—that “[a]t least some” of the amorphous “ZHP Product” “was purchased from Defendant ZHP by John Doe Wholesalers.” Redlined PELMC ¶ 48. These allegations that lump an unknown number of Wholesalers, who may or may not be named Defendants in this case, “do not show that the named Plaintiffs can assert their own direct claim against a *named* Defendant.” MTD Op. 2 (emphasis added).

In an even more problematic example, PMMMC class representative Roland Butler alleges, that of the unknown types of “Aurobindo Product” he purchased, “[a]t least some of this Aurobindo Product was *purchased by either a potential John Doe*

Wholesaler Defendant(s) who then distributed and resold that Aurobindo Product to Retail Pharmacy Defendant Rite Aid (among other Retail Pharmacy Defendants) *or was purchased directly by Rite Aid.*” Redlined PMMMC ¶ 406. (p. 30)⁶ Thus, Plaintiff Butler not only fails to sufficiently allege traceability to any Wholesaler, but also admits it is possible no Wholesaler may even have been involved (as Rite Aid may have directly purchased the product from Aurobindo).

Factually unsupported allegations that some unknown or unnamed Wholesaler(s) may or may not have been linked to “at least some” of an unknown number of unidentified Aurobindo NDCs cannot establish traceability and Article III standing as to the named Wholesalers.⁷ As a result, the Court should dismiss with

⁶ Plaintiffs incorrectly numbered their PMMMC, resulting in paragraph numbers that are duplicated throughout. Where there are duplicate paragraph numbers, Wholesalers have also specified the page number from the PMMMC.

⁷ The unidentified products, missing NDCs, and unsupported references to “John Doe Wholesalers” evidence two possibilities: either Plaintiffs are *not* doing the work required of them by Federal Rule of Civil Procedure 11 and required to cure the standing deficiencies identified by this Court, or Plaintiffs *are* doing the work and have realized that the identity of the products and Wholesalers pertinent to a particular class representative are unknowable. (The latter would be no surprise, as Wholesalers have explained on countless occasions that there is simply no way to trace a particular pill from Manufacturer to end-consumer.) Either way, Plaintiffs should not be granted leave to amend. This case is not new – the first complaints were filed in 2018. Plaintiffs have had years to recruit class representatives and investigate the NDC purchase and sales data Wholesalers produced via discovery. If Plaintiffs are not doing the work required to prosecute this case per the Rules and the Court’s instructions, this Court should not grant Plaintiffs leave to amend. And instead, if Plaintiffs have done the work but the particular product(s) at issue are not

prejudice the claims by the 23 PELMC⁸ and 5 PMMMC⁹ Plaintiffs whose conclusory and untraceable “John Doe” accusations are insufficient to establish Article III standing as to the named Wholesalers, as detailed shown in Mfrs.’ Charts and Wholesalers’ Charts, attached as exhibits to the respective Briefs.

C. Plaintiffs Do Not Establish Standing to Bring State-Law-Based Claims against All or Some Wholesalers in the Majority of Jurisdictions

Wholesalers incorporate fully by reference as if set forth herein the arguments in Mfrs.’ Mem. Section III.B.2 and Pharmacy Defs.’ Mem. Section II.B. In short, Plaintiffs do not allege any basis for standing to assert state-specific claims against Wholesalers to which no plaintiff in that state can trace his or her injury. *Haas v. Pittsburgh Nat’l Bank*, 526 F.2d 1083, 1096 n.18 (3d Cir. 1975) (“a nominal plaintiff

traceable to particular Wholesaler(s), the proposed amendments are futile and leave to amend should be denied.

⁸ The 23 PELMC putative class representatives who made only insufficient “John Doe” allegations as to Wholesalers are: Asha Lamy, Sandra Kelly, Jay Meader, Mark Hays, Charlie Johnston, Marilyn Andre, Peter O’Brien, Estate of Elenora Deutenberg, Lawrence Edwards, Marlin Anderson, Georgia Fatigato, Raleigh Wolfe, Glenda Cooper, Linda Crocker, Jennifer Johnson, Marzanna Glab, Antoinette Sims, James Lawson, James Childs, Radhakrishna Shetty, Brittney Means, Samuel Cisneros, and Mary McLean.

⁹ The 5 PMMMC putative class representatives who made only insufficient “John Doe” allegations as to Wholesalers are: Jo Ann Hamel, Kenneth Berkson, Roland Butler, Valerie Rodich-Annese, and Sylvia Cotton.

may not maintain an action on behalf of a class *against a specific defendant* if the plaintiff is unable to assert an individual cause of action *against that defendant*”) (emphases added). For this reason, as articulated in full in the Manufacturers’ and Pharmacies’ Memoranda, many of the putative class representatives in the PELMC and the PMMMC lack standing to bring specific state-law-based claims against individual Wholesalers. Claims against specific Wholesalers arising out of the law of certain states should be dismissed with prejudice, as outlined in detail shown in Mfrs.’ Charts and Wholesalers’ Charts, attached as exhibits to the respective Briefs.

D. The PELMC’s Third Party Payor Plaintiffs Do Not Allege Standing and Traceability

In the interest of brevity, Wholesalers do not restate the argument here, but instead incorporate by reference as if set forth fully herein the arguments in Mfrs.’ Mem. Section III.B.4. In addition to those arguments, the PELMC includes no revisions whatsoever to link any particular Wholesaler(s) to any alleged injury. Instead, the PELMC simply offers the same conclusory statement (that each Wholesaler sold a large portion of the VCDs at issue to the TPPs) that this Court already held was insufficient to establish traceability and Article III standing. Redlined PELMC ¶¶ 151, 154, 157; MTD Op. 2 (“We cannot conclude the named Plaintiffs injuries are attributable to AmerisourceBergen Corporation from the allegation that it sold ‘a large portion of the adulterated and/or misbranded VCDs that were ultimately paid for by U.S. consumers.’”) (emphasis omitted). For these

reasons, leave to amend should be denied and TPP's claims against Wholesalers should be dismissed with prejudice.

E. The PELMC Continues to Assert an Insufficient Theory of Loss Based on Receipt of a “Less Valuable” Product

Again, Wholesalers do not restate the argument here, but instead incorporate by reference as if set forth fully herein the arguments in Mfrs.' Mem. Section III.B.3. Leave to amend should be denied and Plaintiffs' second theory of economic loss should be dismissed with prejudice.

II. PLAINTIFFS' CONTINUING FAILURE TO PROPERLY PLEAD UNJUST ENRICHMENT CLAIMS IS FATAL IN CERTAIN STATES
(PELMC Counts 11 and 12)

Wholesalers incorporate by reference as if set forth fully herein the arguments in Mfrs.' Mem. Section III.F. This Court should dismiss the unjust enrichment claims against Wholesalers with prejudice in the following 13 states: Alabama, Florida, Hawaii, Idaho, Illinois, Iowa, Kansas, Louisiana, Massachusetts, Mississippi, Oklahoma, South Carolina, and West Virginia.

III. PLAINTIFFS' EXPRESS WARRANTY CLAIMS STILL FAIL DESPITE THE PROPOSED AMENDMENTS *(PPIMC Count 6; PELMC Counts 1 and 2; PMMMC Count 7)*

In MTD Order 3, the Court held that Plaintiffs failed to identify any statement that any Wholesaler made to a Plaintiff that created an express warranty. The Court explained that dismissal of the express warranty claims against Wholesalers was appropriate because none of the master complaints “plead an *express* statement

made by Wholesalers . . . , which can implicate the basis of a bargain with consumer plaintiffs or third party payor plaintiffs. . .” MTD Ord. 3 at 16 (emphasis added). Moreover, the factual allegations in all three master complaints did not include “*specific* statements, conduct, or communications made by Wholesalers . . . which could reasonably imply these defendants made an express warranty to plaintiffs that formed the basis of a bargain.” *Id.* (emphasis added). The Court went on to explain that allegations about Wholesalers’ “mere act of selling a contaminated product” are not sufficient to state a claim for a breach of express warranty because Wholesalers have no obligations with respect to compliance with the Orange Book. *Id.*

The Court’s rulings are clear. Absent factual allegations about express, specific statements made by Wholesalers to Plaintiffs that constituted the basis of a bargain, the breach of express warranty claims fail. Plaintiffs still do not follow the Court’s guidance, and therefore, Plaintiffs’ motion to amend the breach of express warranty claim in all three master complaints should be denied.

A. Plaintiffs Do Not Allege Express, Specific Statements Made By Wholesalers to Plaintiffs to Support Their Breach of Express Warranty Counts (*PPIMC Count 6; PELMC Counts 1 and 2; PMMMC Count 7*)

As the redlines to the PELMC and PMMMC show, Plaintiffs’ allegations in the breach of express warranty counts are virtually identical to Plaintiffs’ prior complaints. *See* redlined PELMC ¶¶ 621-642; redlined PMMMC ¶¶ 655-665. No new facts are alleged, much less *any* facts regarding express, specific statements

made by any Wholesaler to a Plaintiff that constitute a basis of a bargain sufficient to support a breach of express warranty claim. *Id.*

Plaintiffs' breach of express warranty count in the PPIMC is similarly deficient. While Plaintiffs add some conclusory allegations against "Defendants" jointly—namely, an alleged breach of express warranty based on the sale of a generic pharmaceutical that was allegedly not Orange Book compliant—the PPIMC does not allege a single express, specific statement made by any Wholesaler that any Plaintiff read, heard, or relied on. *See* redlined PPIMC ¶¶ 642-659. As such, the breach of express warranty count in the PPIMC remains deficient for the same reasons as before. Allegations that Wholesalers merely sold allegedly contaminated products do not make out an express warranty claim.

Plaintiffs' proposed revisions to the breach of express warranty counts plainly do not satisfy the pleading standard the Court explicitly informed Plaintiffs was necessary. Rather, Plaintiffs' failure to comply with the Court's plain directive to allege express, specific statements made by Wholesalers to Plaintiffs demonstrates that such statements simply do not exist (which is not surprising, as Plaintiffs had no interactions with Wholesalers). Therefore, Plaintiffs' motion to amend the breach of express warranty counts against Wholesalers is futile and should be denied, and those claims should be dismissed with prejudice.

B. Allegations About Publicly Available Statements That Plaintiffs Do Not Allege They Ever Read, Heard, or Relied On Do Not Support Breach of Express Warranty Claims

In an effort to salvage their breach of express warranty counts, Plaintiffs likely will contend that sufficient allegations are contained in Plaintiffs' so-called "Factual Allegations" sections of their proposed amended master complaints. However, rather than providing any allegation that Wholesalers made any express, specific statements, Plaintiffs merely cite to various general, non-valsartan-related statements allegedly published on Wholesalers' websites or located in other publicly-available materials, and allege those generic statements constitute express warranties. They do not. Plaintiffs' amendments in this regard are plainly futile; Plaintiffs do not and cannot connect those public statements to any Plaintiff, and Plaintiffs do not and cannot allege that any of those statements formed the basis of a bargain between a Plaintiff and any Wholesaler. There is no allegation in the hundreds of pages of Plaintiffs' proposed amended master complaints that any Plaintiff read, heard, received, or relied on any of the statements made by Wholesalers, including those generic proclamations counsel gleaned from internet searches and inserted into the proposed amended master complaints.

Moreover, Plaintiffs notably avoid any allegations about *when* the statements plucked from the internet were actually made. Plaintiffs do not and cannot allege that the statements cited were made prior to any Plaintiff's VCD prescriptions such

that they could have been read, heard, and/or relied on in deciding to take a VCD. Indeed, those types of facts can be tricky (and perhaps best omitted) when one is attempting to fashion an express warranty out of statements found on the internet.

Because there is no allegation that the statements attributed to Wholesalers in Plaintiffs’ purported “Fact Sections” were actually read, heard, or relied on by any Plaintiff – or even that those statements *existed* at a time when they could be read, heard, or relied on by a Plaintiff – those statements also cannot be the basis of any bargain upon which a breach of express warranty claim is premised.

C. Electronic Transmissions of Data Are Not Express, Specific Statements Heard, Read, or Relied On By Plaintiffs

Finally, Plaintiffs attempt to resurrect each breach of express warranty claim with a conclusory assertion that “the creation and transmittal of the electronic transaction data record, represent[s] an explicit warranty made by the Wholesaler Defendants to their downstream customers, including [Plaintiffs], that the shipped product was pure valsartan when in fact, it was adulterated and/or misbranded VCDs.” *See* redlined PPIMC ¶ 534; redlined PELMC ¶ 511; redlined PMMMC ¶ 426 (p. 150). This allegation is the same as Plaintiffs’ previously-rejected allegations that Wholesalers merely sold an allegedly contaminated product; it, too, is insufficient to support a claim for breach of express warranty. Further, those electronic transmissions of data are not express, specific statements, and they were not made to any Plaintiff, provided to any Plaintiff, seen by any Plaintiff, or relied

on by any Plaintiff. As such, those electronic data transmissions also cannot form the basis of any bargain between Wholesalers and any Plaintiff.

At bottom, Plaintiffs do not include a single allegation that any Wholesaler made a specific statement to any Plaintiff that formed the basis of a bargain sufficient to support a breach of express warranty claim. The Court should deny Plaintiffs leave to amend the PIMC, ELMC, and MMMC with respect to the breach of express warranty claims against Wholesalers, and dismiss those claims with prejudice.

IV. PLAINTIFFS DO NOT PROPERLY PLEAD THEIR IMPLIED WARRANTY CLAIMS IN ANY OF THE PROPOSED AMENDED COMPLAINTS (*PPIMC Count 7; PELMC Counts 3 and 4; PMMMC Count 6*)

In its MTD Op. 3, the Court dismissed many of Plaintiffs' implied warranty claims in all three master complaints for lack of privity. Plaintiffs' proposed amended implied warranty claims do not correct the deficiencies identified by the Court. Amendment on these counts would be futile and should be denied.

A. The PPIMC Does Not Plead the Required Element of Privity Necessary to State a Claim for Breach of Implied Warranty Under the Laws of Kentucky and Wisconsin

Wholesalers adopt and incorporate herein all arguments made by Manufacturer Defendants with respect to Plaintiffs' failure to cure the lack of privity alleged in the PPIMC and assert claims for breach of implied warranty under the laws of Kentucky and Wisconsin. *See* Mfrs.' Mem., Section III.C.1. Like Manufacturer Defendants, because Plaintiffs did not purchase VCDs from

Wholesalers, there can be no implied warranty claims under Kentucky or Wisconsin law. Those claims should be dismissed.

B. The PELMC and PMMMC Do Not Plead the Required Element of Privity Necessary to State a Claim for Breach of Implied Warranty Under the Laws of Connecticut, Georgia, Illinois, Kansas, Kentucky, and New York

MTD Opinion 3 dismissed without prejudice Plaintiffs' claims in the ELMC and the MMC for breach of implied warranty arising under the law of Arizona, Connecticut, Georgia, Idaho, Illinois, Iowa, Kansas, Kentucky, Michigan, New York, Oregon, Tennessee, Utah, Vermont, and Wisconsin. Plaintiffs attempt to resurrect those claims by purporting to bring breach of implied warranty claims under the laws of every state. *See* redlined PELMC ¶¶ 645, 663; redlined PMMMC ¶ 639. However, neither the PELMC nor the PMMMC includes any putative class representative from Arizona, Idaho, Iowa, Michigan, Oregon, Tennessee, Utah, Vermont, and Wisconsin. As such, as discussed *supra*, no Plaintiff has standing to assert claims for breach of implied warranty under the laws of those states, and Plaintiffs have failed to properly amend the PELMC and PMMMC to assert claims for breach of implied warranty under the laws of those states.

With respect to class representative Plaintiffs who are attempting to assert claims for breach of implied warranty from Connecticut, Georgia, Illinois, Kansas, Kentucky, and New York, the allegations in the PELMC and PMMMC still lack the “required element” of privity. MTD Op. 3 at 22. Plaintiffs instead attempt to

circumvent this mandatory element with a conclusory allegation that they are “third-party beneficiaries” of all contracts between the Manufacturer Defendants and Wholesalers and Retailer Defendants. Redlined PELMC ¶¶ 651-53, 666-68; redlined PMMMC ¶¶ 645-47. Plaintiffs’ effort to evade the privity requirement fails. The states for which Plaintiffs must plead privity have either not found a third-party beneficiary exception to the privity requirement, rejected such arguments, or found allegations similar to those in the PELMC and the PMMMC insufficient.

In Kansas, implied warranties extend only to persons “who suffer personal, as opposed to economic, injury,” and therefore do not cover third-party beneficiary economic injury claims. *See Limestone Farms, Inc. v. Deere & Co.*, 29 P.3d 457, 461 (Kan. Ct. App. 2001) (rejecting plaintiffs’ intended third-party beneficiary implied warranty claims). Kentucky also only extend third-party beneficiary status to plaintiffs in personal injury actions. *See Simpson v. Champion Petfoods USA, Inc.*, 397 F.Supp.3d 952, 964-65, 969 (E.D. Ky. June 21, 2019) (rejecting the extension of third-party beneficiary status to plaintiffs in economic loss cases under Kentucky law). New York law is the same. *See Hole v. General Motors*, 83 A.D.2d 715, 716, 442 N.Y.S.2d 638, 640 (App. Div. 1981) (Section 2–318 of the Uniform Commercial Code . . . “does not permit a plaintiff, not in privity, to recover upon the breach of an implied warranty of merchantability unless the claim of the remote user is for personal injuries.”)

In Georgia, “if a defendant is not the seller to the plaintiff-purchaser, the plaintiff as the ultimate purchaser cannot recover on the implied or express warranty, if any, arising out of the prior sale by the defendant to the original purchaser, such as distributor or retailer from whom plaintiff purchased the product.” *Evershine Prods. Inc. v. Schmitt*, 130 Ga.App. 34, 35 (1973); *see also Ellis v. Rich’s*, 233 Ga. 573 (1975). The Uniform Commercial Code (UCC) as adopted in Georgia has extended warranty protection to certain limited types of third-party beneficiaries, but Plaintiffs here do not qualify. Specifically, a seller’s warranty, whether express or implied, extends to any natural person in the family or household of the buyer or who is a guest in the buyer’s home if it is reasonable to expect that such person may use, consume, or be affected by the goods and who is injured in person by breach of the warranty.

Similarly, in Connecticut, an action for economic loss caused by a product may be brought only under Title 42a of the Uniform Commercial Code. *See* CT Gen. Stat. §52-572n(c). Privity is essential to a warranty claim asserted pursuant to CT Gen Stat. §§42a-2-314 and 42a-2-315. Where a product is not sold to a plaintiff, there is no privity. *See Garthwait v. Burgio*, 153 Conn. 284, 286 (1965). CT Gen. Stat. §42a-2-318 provides a third-party exception to the privity requirement by extending the coverage of a seller's warranty to natural persons who are members of the buyer's household or guests in his home and who seek personal injury damages.

Putative class representative plaintiffs in the PELMC and PMMMC clearly do not fit the definition of third-party beneficiaries to any implied warranty that accompanied Wholesalers' sale of any VCD to a Pharmacy Defendant under Georgia or Connecticut law. These class representatives are not a member of the family or household of any Pharmacy Defendant from which they purchased a VCD, nor do they qualify as a guest. They also do not seek damages for personal injuries.

Under the law of Illinois, privity of contract is a prerequisite to recover economic damages for breach of implied warranty. *See Voelker v. Porsche Cars N. Am., Inc.*, 353 F.3d 516, 525 (7th Cir. 2003) (citing *Rothe v. Maloney Cadillac, Inc.*, 119 Ill.2d 288 (1988)); *Szajna v. General Motors Corp.*, 115 Ill.2d 294 (1986). In *Elward v. Electrolux Home Prods., Inc.*, 214 F.Supp.3d 701, 705-06 (N.D. Ill. 2016), the Court discussed a third-party beneficiary exception, "which applies where the manufacturer knew the identity, purpose and requirements of the dealer's customer and manufactured or delivered goods specifically to meet those requirements." (internal citations and quotation omitted). In *Rhodes Pharmacal Co. v. Continental Can Co.*, 72 Ill.App.2d 362, 372 (1966), the Illinois Court of Appeals held that the third-party beneficiary doctrine should be applied "to a situation where a seller makes a product for a user who is not a direct buyer, but with whom the seller has

direct dealings.”¹⁰ (emphasis added). Here, Plaintiffs do not allege that they had any “direct dealings” with Wholesalers. Indeed, class Plaintiffs have generally never heard of Wholesalers and have no idea what Wholesalers do. Therefore, Plaintiffs in the PELMC and PMMMC have not and cannot allege a claim for breach of implied warranty against Wholesalers under Illinois law.

Because the PELMC and PMMMC do not allege direct privity between Plaintiffs and Wholesalers, and do not allege any cognizable third-party beneficiary exception under the applicable states’ laws, Plaintiffs’ implied warranty claims are futile in those states requiring privity. Leave to amend should be denied and the PELMC’s and PMMMC’s implied warranty claims under the laws of Arizona, Connecticut, Georgia, Idaho, Illinois, Iowa, Kansas, Kentucky, Michigan, New York, Oregon, Tennessee, Utah, Vermont, and Wisconsin against Wholesalers should be dismissed with prejudice.

V. PLAINTIFFS’ PROPOSED AMENDMENTS TO THE FRAUD CLAIMS AGAINST WHOLESALERS STILL DO NOT MEET THE HEIGHTENED PLEADING STANDARD FOR FRAUD CLAIMS
(PELMC Counts 5, 6, 9, and 10; PMMMC Count 8; PPIMC Counts 8 and 10)

¹⁰ The Illinois Supreme Court has not recognized any exception to the privity requirement, including a third-party exception. *See Manley v. Hain Celestial Grp., Inc.*, 417 F.Supp.3d 1114, 1123 (N.D. Ill. 2019) (“This Court is not alone in doubting the Illinois Supreme Court would recognize any exceptions to the requirement of privity for implied warranty claims.”) (citing *Caterpillar, Inc. v. Usinor Industeel*, 393 F.Supp.2d 659, 678 (N.D. Ill. 2005)).

Wholesalers assert and incorporate the arguments against Plaintiffs’ fraud claims discussed in Pharmacy Defs.’ Mem. Section I.C as though fully set forth herein. In addition, with Plaintiffs’ proposed amended complaints now before the Court, it is clear they do not meet the heightened pleading standard for fraud claims and, therefore, Plaintiffs’ motion to amend should be dismissed as futile.¹¹ *See, e.g., Trusted Transp. Sols., LLC v. Guar. Ins. Co.*, No. 16-cv-7094, 2019 U.S. Dist. LEXIS 164871, at *7 (D.N.J. Sept. 25, 2019) (affirming Order denying Plaintiff’s Motion for Leave to File a Second Amended Complaint where “Judge Schneider reasonably concluded that Count X of the Proposed Second Amended Complaint did not satisfy Rule 9(b).”); *S. Jersey Gas Co. v. Mueller Co., LTD*, No. 09-4194, 2011 U.S. Dist. LEXIS 133829, at *19-22 (D.N.J. November 18, 2011) (denying leave to amend where the proposed amended complaint did not “allege[] any facts to satisfy the heightened pleading requirement of Rule 9(b)”), *aff’d*, No. 12-1547, 2013 U.S. App. LEXIS 4822, at *4 (3d Cir. Mar. 11, 2013); *Tadros v. City of Union City*, No.

¹¹ The Third Circuit, in *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1435 (3d Cir. 1997), noted that that “[o]rdinarily where a complaint is dismissed on Rule 9(b) ‘failure to plead with particularity’ grounds alone, leave to amend is granted.” However, the Court in *In re Burlington* did not have the benefit of plaintiff’s proposed amendments before it. Courts in the District of New Jersey have consistently denied motions to amend where, with the benefit of Plaintiffs’ proposed amendments before the Court, the Court was able to determine that the proposed amendments did not meet the Rule 9(b) standard and would therefore be futile. This Court should do the same.

10-CV-2535, 2011 U.S. Dist. LEXIS 35714, at *23-26, 35-36 (D.N.J. Mar. 31, 2011) (denying motion to amend where proposed amended complaint did not satisfy heightened pleading requirements of plaintiff's RICO, billing fraud and common law fraud claims); *Gibbs v. Massey*, No. 07-3604 (PGS), 2009 U.S. Dist. LEXIS 23578, at *19 (D.N.J. Mar. 26, 2009) (denying leave to amend where plaintiff failed "to meet the heightened pleading standard . . . for claims grounded in fraud.").

As with the express warranty claims, Plaintiffs do not add sufficient detail to their fraud claims to cure the deficiencies identified by the Court. *See* MTD Op. 4 at 18-21. Despite explicit instructions by the Court as to the requirements for properly pleaded fraud claims (*See* MTD Op. 4 at 20, § 4.2), Plaintiffs' fraud claims remain insufficiently pled under both Rule 9(b) and Rule 8. None of Plaintiffs' amendments provide the requisite particularity as to the (1) "who, what, where, or when" of the alleged fraudulent statements or omissions; (2) Wholesalers' knowledge, either collectively or individually, that their representations were false or misleading; or (3) Plaintiffs' reliance on the alleged false statements, misrepresentations, or omissions. *See, e.g.*, redlined PELMC ¶¶ 511-512, 691-692; redlined PMMMC ¶¶ 423-427 (pp. 148-150), 670-673; redlined PPIMC ¶¶ 454-486; 531-536. Finally, Plaintiffs do not allege facts demonstrating any special relationship between Wholesalers and Plaintiffs giving rise to a duty to disclose that is required in order to successfully plead fraud by omission. For these reasons, as well as those stated in

the Pharmacy Defs.’ Mem. Section I.C, which Wholesalers incorporate by reference as if set forth fully herein, all claims based on fraud should be dismissed with prejudice against Wholesalers.

A. Plaintiffs Still Do Not Plead the Specifics of Any Alleged Fraudulent Statement or Misrepresentation

Despite the Court’s instructions, Plaintiffs still “do not allege the ‘who, what, where, or when’ necessary to satisfy the particularity requirement of Rule 9(b).” MTD Op. 4 at 19-20, § 4.2. As before, the majority of “the allegations lump all of the defendants together[,]” alleging generally that “each Defendant” or “Defendants” collectively made fraudulent or misleading representations, but mention no specific facts regarding intentional misrepresentations or omissions made by any Wholesaler in particular. MTD Op. 4 at 1. Plaintiffs continue to “lump” unspecified “Defendants” in the operative causes of action, as well as throughout the complaints generally. *See, e.g.*, redlined PELMC ¶ 677; redlined PMMMC ¶ 672; redlined PPIMC ¶ 674. The fact that Plaintiffs added language—which lumps only the group of “Wholesaler Defendants” together, without distinguishing between them—does not remedy this deficiency. *See, e.g.*, redlined PELMC ¶ 677; redlined PMMMC ¶ 423 (p. 148)¹²; redlined PPIMC ¶ 454. As the Court previously noted,

¹² Plaintiffs similarly lumped Wholesalers together in their Second Amended Economic Loss Class Action Complaint, which the Court previously determined did not sufficiently specify “who” made the alleged misstatements. *See* ELMC ¶ 411.

“[t]his failure is detrimental to [P]laintiffs’ fraud claim because *notice* is the main purpose of Rule 9(b)’s particularity requirement.” MTD Op. 4 at 19, § 4.2 (emphasis added).

Moreover, on the rare occasions where Plaintiffs refer to a particular Wholesaler, Plaintiffs still do not identify “the time, place, [or] content of the statement with any level of particularity nor do they inject precision or a measure of substantiation into their allegations other than merely saying so.” MTD Op. 4 at 19, § 4.2. At best, Plaintiffs include a sprinkling of unsubstantiated allegations containing so-called “statements” and “representations,” none of which contain the requisite particularity. *See, e.g.*, redlined PMMMC ¶¶ 370, 423-435 (pp. 148-150). For example, Plaintiffs state that “Defendants affirmatively misrepresented material facts including *inter alia*, that their VCDs were therapeutically equivalent to their RLDs and/or complied with cGMPs and/or were not contaminated, adulterated, and/or misbranded.” *See id.* ¶ 672; *see also, e.g.*, redlined PELMC ¶ 677. While these allegations loosely describe what the alleged misrepresentations were *about*, they do not set forth the actual *content* of any alleged fraudulent statement.

And where actual content is alleged, the allegedly fraudulent statements and/or misrepresentations are only ‘fraudulent’ because Plaintiffs say so. For example, Plaintiffs allege that Wholesalers provide “Pharmacy Defendants with

transaction data that describes the shipping date of the tote, the number of containers, the Lot Numbers, the NDCs, the name of the API or Finished Dose Manufacturer, and the description of the product itself.” *See* redlined PELMC ¶ 508. Correctly, Plaintiffs note that Wholesalers include an affirmative statement with such data, indicating that “[Wholesaler] has complied with each applicable section of FDCA Sec. 581(27)(A)-(G).” *Id.* at ¶ 509. This form statement is required to be included in each “transaction statement” by the Drug Supply Chain Security Act (“DSCSA”). FDCA Sec. 581(27)(A)-(G). But Plaintiffs extrapolate, based on nothing more than pure conjecture, that this mandatory transaction statement constitutes an “explicit warranty made by the Wholesaler Defendants to their downstream customers, including Class Plaintiffs, that the shipped product was pure valsartan[.]” *See* redlined PELMC ¶ 511; redlined PMMMC ¶¶ 425-426 (pp. 149-150) (same). However, compliance with the DSCSA’s transaction statement requirements cannot conceivably be read to constitute such an express warranty. If Plaintiffs’ unsubstantiated additions to their proposed amended complaints demonstrate anything, it is their inability to allege even one fraudulent statement made by any one Wholesaler.

Finally, even if Plaintiffs *had* included the content of Wholesalers’ alleged fraudulent statements, they still do not indicate the time or place such alleged statements were made, other than including a catch-all reference to hypothetical

routes through which the alleged fraudulent statements were allegedly communicated. *See, e.g.*, redlined PELMC ¶ 677 (listing “package inserts, medication guides, instructions for use, and [] transaction data” as well as “websites, brochures, and other marketing or information material.”). Instead, Plaintiffs only quote generally to supply-chain-related statements made by Wholesalers, none of which constitute alleged fraudulent statements regarding VCDs. *See, e.g.*, redlined PELMC ¶ 537.

Plaintiffs’ allegations remain vague and do not put Wholesalers on notice as to the actual misrepresentations or omissions they are alleged to have made; the allegations come nowhere near the level of specificity required to plead fraud. For these reasons, leave to amend should be denied and the fraud claims against Wholesalers in the PPIMC, the PELMC, and the PMMMC should be dismissed with prejudice.

B. Plaintiffs Do Not Allege that Wholesalers Knew of the Alleged Defects

Plaintiffs still do not meet either the Rule 9(b) or Rule 8 standards for requisite knowledge. Instead, Plaintiffs merely add non-specific, conclusory allegations—some of which are entirely unrelated to the instant litigation—regarding Wholesalers’ alleged knowledge, without any factual basis. For example, Plaintiffs make much of Wholesalers’ requirements under the DSCSA, as well as the information provided to Wholesalers by Manufacturers under the DSCSA

(“transaction data”). *See* redlined PELMC ¶¶ 505-506; redlined PMMMC ¶ 423 (p. 148). But nowhere in Plaintiffs’ proposed amended complaints is there any substantiated allegation as to how any such transfer of information would have, or should have, led to Wholesalers’ actual knowledge of the adulteration, misbranding, or contamination of VCDs. *See also, e.g.*, redlined PELMC ¶¶ 498, 502, 534, 546, 554; redlined PMMMC ¶ 467 (p. 159), 471 (p. 161); redlined PPIMC ¶ 521. As Plaintiffs include only conclusory allegations regarding knowledge on the part of Wholesalers, the Court should dismiss Plaintiffs’ fraud claims with prejudice.

C. Plaintiffs Do Not Plead Reliance

Despite the clear guidelines set forth by the Court regarding these facts that “are indisputably within plaintiffs’ control,” Plaintiffs still fail to link the alleged reliance of any Plaintiff to any actual statement, representation, or omission by Wholesalers. *See* MTD Op. 4 at 20, § 4.2. Instead, Plaintiffs attempt to remedy this deficiency by simply adding more conclusory statements to their pleadings, none of which satisfy the particularity requirement. *See, e.g.*, redlined PELMC ¶¶ 49, 513; redlined PMMMC ¶¶ 402 (p. 21), 427 (p. 150), 678; redlined PPIMC ¶ 536. Plaintiffs’ fraud claims should be dismissed with prejudice for this additional reason.

D. Plaintiffs’ Fraud by Omission Claims Do Not Meet the Rule 8 Standard and Do Not Allege Any Duty to Disclose Owed by Wholesalers

For all of the reasons stated herein, in Pharmacy Defs.’ Mem. Section I.C, and in the Court’s MTD Opinion 4, Plaintiffs’ fraudulent concealment claims fail to meet the standard for pleading under Rule 8. In addition to those arguments, Plaintiffs do not remedy their failure to allege that Wholesalers owed the requisite duty to disclose by virtue of a fiduciary or trust-based relationship between the parties. *See* ECF No. 522-1, at 24-25. Plaintiffs still do not, and indeed, cannot, include facts alleging that a fiduciary relationship exists between Plaintiffs and Wholesalers. *Arcand v. Brother Int’l Corp.*, 673 F.Supp.2d 282, 305 (D.N.J. 2009). For this additional reason, the Court should dismiss Plaintiffs’ claims of fraudulent concealment and omission.

E. Plaintiffs’ State Consumer Fraud Claims Remain Inadequately Pled

As the Court noted, Plaintiffs’ claims for alleged violations of consumer protection statutes are subject to the same heightened pleading standard of Fed. R. Civ. P. 9(b) applicable to Plaintiffs’ fraud claims, as discussed *supra*. *See* MTD Op. 4 at 19 n.9, § 4.2. Plaintiffs’ consumer fraud claims remain insufficiently pleaded for the same reasons set forth herein as to all other fraud-based claims. In short, Plaintiffs fail to provide the specificity required by Rule 9(b) to state an actionable claim for a violation of any consumer protection statute against Wholesalers.

VI. PLAINTIFFS DO NOT INCLUDE FACTS SUFFICIENT TO SUPPORT NEGLIGENT MISREPRESENTATION/OMISSION CLAIMS AGAINST WHOLESALERS (PPIMC Count 9; PELMC Counts 7 and 8; PMMMM Count 3)

The Court agreed with Wholesalers that Plaintiffs' original negligent misrepresentation claims were "essentially a boilerplate list of legal conclusions," because Plaintiffs failed to explain how Wholesalers communicated or otherwise made the purported misrepresentations to Plaintiffs regarding VCDs. MTD Op. 4 at 21. Plaintiffs' proposed amended master complaints fare no better.

Plaintiffs propose adding allegations suggesting that Wholesalers made misrepresentations to Plaintiffs either (1) in the product labeling and package inserts, which contain FDA-approved information controlled exclusively by the Manufacturing Defendants; (2) in the transaction data accompanying the product; and (3) in general statements published on Wholesalers' websites and marketing materials regarding product safety that do not mention VCDs whatsoever. *See, e.g.*, redlined PELMC ¶ 710 ("These misrepresentations were present on, among other things, the VCD labels, patient package inserts, medication guides, instructions for use, and the transaction data produced by the Wholesaler Defendants . . . The Defendants further misrepresented material facts by lauding their safety and risk mitigation approaches on their websites, brochures, and other marketing or informational materials."); redlined PPIMC ¶¶ 689-90 (similar); redlined PMMMC ¶ 599 (similar, but lumping all Defendants together, without noting where Wholesalers specifically misrepresented information).

Plaintiffs’ allegations regarding purported misrepresentations made through product labelling and package inserts do not support a claim for negligent misrepresentation as to Wholesalers. The labelling and other package information accompanying VCDs is authored by Manufacturers, and Plaintiffs acknowledge as much. *See, e.g.,* redlined PELMC ¶ 416. Wholesalers have no control over the product labeling or its contents, which may only be changed by the product’s manufacturer through FDA approval. As such, Plaintiffs’ negligent misrepresentation claims as to Wholesalers, based on statements contained in product labeling and package inserts, must be dismissed. *See Smith v. Teva Pharms. USA, Inc.*, 437 F.Supp.3d 1159, 1166 (S.D. Fla. 2020) (dismissing products liability, negligence, and negligent failure to warn claims against a distributor, finding that the distributor was “powerless to submit label changes to the FDA.”); *Scanlon v. Medtronic Sofamor Danek USA Inc.*, 61 F.Supp.3d 403, 411–12 (D. Del. 2014) (dismissing negligent misrepresentation cause of action as preempted, where the material facts alleged by the plaintiffs to be missing from the product label “would require a change in those warnings or disclosures required by the FDA.”).

Plaintiffs also allege that Wholesalers made negligent misrepresentations in “the transaction data produced by the Wholesaler Defendants,” which Plaintiffs describe as “electronic records and manifests that provide the details of the product being shipped,” including “a record of the product’s ship date, contents, NDC, Lot

number, and the name of the product itself.” *See, e.g.*, redlined PELMC ¶¶ 505-06. But Plaintiffs fail to specify what part of this transaction data constitutes a misrepresentation, and most importantly, do not allege that Plaintiffs ever received or saw that transaction data. Plaintiffs allege that Wholesalers provided the transaction data to the Pharmacy Defendants but do not (and cannot) allege that this information was ultimately disseminated to Plaintiffs. *See, e.g.*, redlined PELMC ¶ 508 (“For example, Cardinal Health provides ***Pharmacy Defendants*** with transaction data”) (emphasis added); redlined PPIMC ¶ 531 (similar). Plaintiffs’ failure to explain how Wholesalers communicated the purported misrepresentations in the transaction data to Plaintiffs is fatal to their claim.

Finally, Plaintiffs allege that Wholesalers made negligent misrepresentations by “lauding their safety and risk mitigation approaches on their websites, brochures, and other marketing or informational materials.” *See, e.g.*, redlined PELMC ¶ 710. Tellingly, Plaintiffs do not allege that any of these purported representations were made with respect to VCDs. Generic statements are insufficient to state a claim for negligent misrepresentation. *See Glen Holly Ent., Inc. v. Tektronix, Inc.*, 352 F.3d 367, 379 (9th Cir. 2003) (affirming dismissal of negligent misrepresentation claims where “[t]he statements were generalized, vague and unspecific assertions . . . upon which a reasonable consumer could not rely.”) Plaintiffs’ Motion to Amend with respect to negligent misrepresentation allegations should thus be denied as futile,

and the negligent misrepresentation claims as to Wholesalers should be dismissed with prejudice.

VII. PLAINTIFFS’ NEGLIGENCE CLAIMS ARE STILL INSUFFICIENTLY PLED AS TO WHOLESALERS (*PPIMC Count 4; PELMC Counts 13 and 14; PMMMC Count 1*)

Wholesalers do not restate the argument here, but incorporate fully by reference as if set forth herein the arguments in Pharmacy Defs.’ Mem. Section I.B. In addition, the Court dismissed Plaintiffs’ negligence claims as to Wholesalers because “the Master Complaints are devoid of factual allegations” to support the purported duties of care identified by Plaintiffs in their briefing, and further because “the Master Complaints lump Defendants together with conclusory allegations,” and “fail to precisely articulate the duty that . . . the Wholesaler Defendants owed to Plaintiffs and the specific breach that occurred.” MTD Op. 5 at 32. Plaintiffs’ proposed amendments do not address the deficiencies identified by the Court, are thus futile for failure to state a claim, and Plaintiffs’ negligence claims against Wholesalers should be dismissed with prejudice.

In the PELMC and PMMMC, Plaintiffs again fail to precisely articulate any duty owed to them by Wholesalers. Rather than follow the guidance of the Court, Plaintiffs instead leave in place their prior allegations regarding duty, which lump all Defendants together, and fail to add any new allegations to the negligence counts. *See, e.g.,* redlined PELMC ¶ 788 (“Each Defendant owed a duty to Plaintiffs and the

Class to use and exercise reasonable and due care in the manufacturing of its VCDs”); redlined PMMMC ¶ 573 (“Each Defendant owed a duty to Plaintiffs and the Classes to use and exercise reasonable and due care in the manufacturing, testing, distribution, labeling, marketing, warnings, disclosures, and sale of its VCDs”). Wholesalers do not manufacture VCDs; as such, blanket conclusory allegations regarding the duty of “[e]ach Defendant” to exercise reasonable care in manufacturing is misplaced with respect to Wholesalers, and highlights the deficiency in Plaintiffs’ allegations that do not distinguish between the specific duties owed by the different tiers of Defendants. These conclusory allegations of duty as to all Defendants fail to state a claim as to Wholesalers; thus, the proposed amendments to the ELMC and MMC should be denied as futile, and the negligence claims should be dismissed with prejudice.¹³

In the PPIMC, Plaintiffs now allege that Wholesalers “owed Plaintiffs a duty to exercise reasonable care in vetting their generic manufacture suppliers to ensure they did not sell adulterated, misbranded, and/or contaminated product” and “owed Plaintiffs a duty to exercise reasonable care in their acquisition and re-sale of products.” Redlined PPIMC ¶ 623. However, Plaintiffs continue to recite conclusory

¹³ To the extent Plaintiffs contend that allegations that “Wholesaler Defendants failed to take any steps to test” VCDs support a cognizable duty, e.g., redlined PELMC ¶ 144, the Court has already determined that such allegations fail to properly plead a duty as to Pharmacy Defendants and Wholesalers. MTD Op. 5 at 31-32.

allegations regarding Wholesalers’ purported breach of those duties – simply stating that Wholesalers “failed to conduct due diligence on their generic suppliers” and failed “to exercise reasonable care in their acquisition and re-sale of products.” *Id.* ¶ 624. The PPIMC remains devoid of factual allegations to support those statements. Thus, the Court should likewise find that Motion to Amend with respect to the PPIMC should be denied as futile, and dismiss Plaintiffs’ negligence claims as to Wholesalers with prejudice.

VIII. PLAINTIFFS DID NOT AMEND THE MMMC FAILURE TO WARN COUNT TO COMPORT WITH THE COURT’S ORDER (PMMMC Count 5)

The Court dismissed with prejudice Plaintiffs’ strict liability failure to warn claims in the PIMC and MMMC that arise under the laws of states that prohibit strict liability failure to warn claims – namely, Virginia, Pennsylvania, North Carolina, Massachusetts, and Delaware. MTD Ord. 4 at 3; MTD Op. 4 at 26. Nonetheless, Plaintiffs failed to change the Failure to Warn cause of action in the PMMMC to exclude claims arising under the laws those states. *See* redlined PMMMC, Fifth Claim for Relief, ¶¶ 631-636. Plaintiffs’ failure to warn causes of action in the PMMMC should therefore be dismissed with prejudice as to claims arising under the laws of Virginia, Pennsylvania, North Carolina, Massachusetts, and Delaware.

IX. PLAINTIFFS DID NOT AMEND THE ELMC AND MMMC NEGLIGENCE PER SE COUNTS TO COMPORT WITH THE COURT’S ORDER (PELMC Counts 15 and 16; PMMMC Count 2)

Wholesalers assert and incorporate the arguments against Plaintiffs' negligence per se claims set forth in Section III.E of Mfrs.' Mem. Pursuant to this Court's prior order and opinion, MTD Order 5 at 5 and MTD Opinion 5 at 30, the Court should dismiss with prejudice Plaintiffs' negligence *per se* claims in the PELMC and PMMMC arising under the laws of Arkansas, Arizona, California, Massachusetts, Maine, Nebraska, Rhode Island, and Texas.

X. PLAINTIFFS SHOULD NOT BE GRANTED LEAVE TO AMEND CLAIMS DERIVATIVE OF THE CLAIMS IDENTIFIED IN SECTIONS III-VII (*PPIMC Counts 12, 13, 14, and 15*)

Because Plaintiffs should not be granted leave to amend as to the claims identified in Sections III-VII (*PPIMC Counts 4, 6, 7, 8, 9, and 10*), Plaintiffs should also be denied leave to amend all derivative claims (e.g., wrongful death, survival, loss of consortium, and punitive damages), as such causes of action "cannot be actionable." MTD Op. 6 at 15.

CONCLUSION

WHEREFORE, for the foregoing reasons, as well as those reasons applicable to Wholesalers as outlined in the co-Defendants' briefs and adopted herein, Wholesalers respectfully request that Plaintiffs' motion for leave to amend be denied as futile, and that the previously dismissed claims asserted in three original Master Complaints be dismissed with prejudice against Wholesalers.

Dated: May 27, 2021

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 27th day of May, 2021, I filed the foregoing **WHOLESALE DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION FOR LEAVE TO AMEND MASTER COMPLAINTS** electronically through the CM/ECF system, which will send notice of filing to all CM/ECF participants.

/s/ Marie S. Dennis
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